

510(k) Summary

K001509

10/26/01

SUBMITTER: Stöckert Instrumente GmbH
Division of Sorin Biomedica SpA
Lilienthalalle 5-7
D-80939 Munich Germany

APPLICANT: COBE Cardiovascular, Inc.
Division of Sorin Biomedica SpA
14401 W. 65th Way
Arvada, Colorado 80004-3599 USA

CONTACT PERSON: Lynne Leonard
Regulatory and Clinical Affairs Manager
COBE Cardiovascular, Inc.
Arvada, Colorado USA
Phone: (303) 467-6586
Fax: (303) 467-6429

DATE PREPARED: May 10, 2000

DEVICE TRADE NAME: Stöckert V172 Series Venous Femoral Cannulae

COMMON/USUAL NAME: Cardiovascular Femoral Cannulae

CLASSIFICATION NAME: Cardiopulmonary Bypass Vascular Catheter, Cannula or Tubing

PREDICATE DEVICE: Medtronic DLP Venous Femoral Cannulae

DEVICE DESCRIPTION:

The Stöckert V172 Series Venous Femoral Cannulae are sterile, non-pyrogenic devices, for single use only, and are not to be resterilized by the user. The devices are polyvinyl chloride (PVC) wire reinforced cannulae with a non-wire reinforced proximal end for clamping and for connecting the device to a cardiopulmonary bypass circuit. The Stöckert V172 Series cannulae are intended to be used to cannulate the femoral venous vessels during cardiopulmonary bypass surgery. During use, the cannula is inserted into the vena femoralis and advanced into the right atrium, allowing blood from the systemic circulation to enter the extracorporeal circuit. Insertion of the cannula into the vena femoralis during cardiopulmonary bypass surgery is an alternative method for insertion of a cannula into the superior or inferior vena cava.

The Stöckert V172 Series cannulae are offered in two sizes. The smaller size is 22 Fr and 70 cm in length, with a flexible proximal end that can accommodate either a 3/8" or 1/2" connector. The larger size is 28 Fr and 90 cm in length, with a flexible proximal end that can accommodate a 1/2" connector. The cannula tube contains two sets of side holes, one set for drainage from the right atrium and one set for drainage from the inferior vena cava and hepatic veins. An obturator is provided with each cannula, which seals the inside of the cannula tube in the areas of the side holes to prevent blood leakage from the cannula during insertion. After insertion, the obturator is removed and discarded by the user.

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INDICATIONS FOR USE

The Stöckert V172 Series Venous Femoral Cannulae are intended to be used to cannulate the femoral venous vessels during cardiopulmonary bypass surgery.

STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The Stöckert V172 Series Venous Femoral Cannulae are substantially equivalent to the Medtronic DLP Venous Femoral Cannulae. The following tests were performed to demonstrate substantial equivalency of the devices:

1. Pressure Drop
2. Blood Trauma
3. Leak
4. Kink Resistance



OCT 26 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stockert Instrumente GmbH
c/o Mr. Shawn Riedel, Regulatory Affairs/Quality Assurance Manager
COBE Cardiovascular, Inc.
14401 W. 65th Way
Arvada, CO 80004-3599

Re: K001509
Trade Name: Stockert V172-22 Venous Femoral Cannulae, size 22 French
Regulation Number: 21 CFR 870.4210
Regulatory Class: Class II
Product Code: DWF
Dated: July 27, 2001
Received: July 30, 2001
Amended: October, 22, 2001

Dear Mr. Riedel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

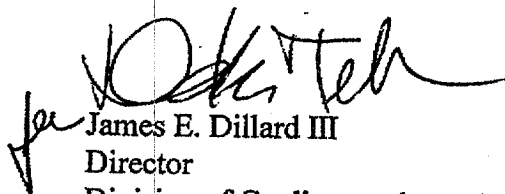
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. Shawn Riedel

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,


James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (If known): K001509

Device Name:


Stöckert V172-22 Venous Femoral Cannulae

Indications For Use:

The Stöckert V172-22 Venous Femoral Cannulae are intended to be used to cannulate the inferior vena cava and the right atrium, via femoral venous access, during cardiopulmonary surgery for periods of up to six hours.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K001509

Prescription Use ☒
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐